K122232(113)

Medacta International

SEP 28 2012

510(k) Summary

Applicant/Sponsor: Medacta International SA
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Contact Person: Mr. Adam Gross
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Date Prepared: July 20, 2012

DEVICE INFORMATION

Trade/Proprietary Name: GMK Narrow
Common Name: Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3560
Class II
Device Product Codes: JWH

Predicate Devices:

K090988 GMK Total Knee System (Medacta International)
K120790 GMK - Line Extension (Medacta International)

Product Description

The GMK Narrow Femoral Components are intermediate sizes within the 510(k) cleared size range of the K090988 GMK Total Knee System. GMK Narrow components are designed with the same AP dimension as the correspondent K090988 GMK Total Knee System components (from Size 2 to Size 6) but with a reduced ML dimension of 4 mm. The reduced ML dimension of 4mm corresponds to an "X-1" size of the K090988 GMK Femur in the ML plane. The articular surfaces profile remains the same as the existing femoral components, both for the condyles and the trochlear groove. GMK Narrow Femoral Components are provided in the STD cemented version (to be used with STD and UC fixed tibial inserts) and in the PS cemented version (to be used with PS fixed tibial inserts).

Indications for Use

The GMK knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

Comparison to Predicate Devices

The indications for use of the GMK Narrow are identical to K120790 GMK - Line Extension. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. In terms of design features, GMK Narrow components are designed with the same AP dimension as the correspondent K090988 GMK Total Knee System femoral components (from Size 2 to Size 6) but with a reduced ML dimension of 4 mm. The reduced ML dimension of 4mm corresponds to an "X-1" size of the K090988 GMK Femur in the ML plane. The articular surfaces profile remains the same as the existing femoral components, both for the condyles and the trochlear groove. In terms of materials, GMK Narrow components are made from Cobalt Chromium Molybdenum (CoCrMo) according to ISO5832-4:1996, Implants for Surgery -

Metallic materials – Part 4: Cobalt-chromium-molybdenum Casting Alloy which is the same as the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the GMK Narrow are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

GMK Narrow was evaluated using finite element method (FEM) analysis to demonstrate that the GMK Narrow Femoral Components do not represent worst case conditions compared to the predicate devices and that no further mechanical tests are necessary.

The modification to the device system to include the addition of the GMK Narrow was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The testing was compared to the worst case component size and option/design based on engineering analysis. The GMK Narrow was compared to the worst case K090988 GMK Total Knee components in terms of stress distribution, ROM, constraints, mobility and wear behavior and it was determined that the GMK Narrow femoral components are not worst case.

Conclusion:

Based on the above information, the GMK Narrow can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medacta International
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Mr. Adam Gross
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SEP 28 2012

Re: K122232
Trade/Device Name: GMK Narrow
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 28, 2012
Received: August 29, 2012

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

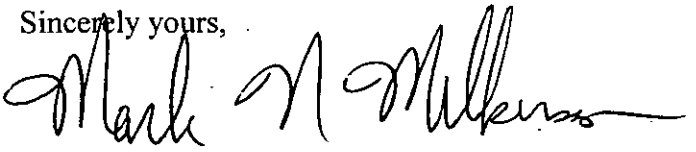
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122232 (1/1)

Indications for Use

510(k) Number (if known):

Device Name: GMK Narrow

Indications for Use:

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Prescription Use ____x____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices